REMARKS

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1-25 are pending in this application. Claims 9, 13, 17, 20, 22 and 23 are amended. Claims 24 and 25 are added to replace cancelled claims 10 and 11. No new matter is added.

It is submitted that the claims are patentably distinct over the prior art and that these claim are and were in full compliance with the requirements of 35 U.S.C. § 112. The amendments of the claims are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but simply for clarification and to round out the scope of protection to which Applicants are entitled. Furthermore, it is explicitly stated that these amendments should not give rise to any estoppel, as they are not narrowing amendments.

II. THE RESTRICTION REQUIREMENT SHOULD BE REDRAWN

The Office Action requires an election under 35 U.S.C. § 121 from among the following:

Group I: Claims 1 (in part) and 3-5, drawn to a composition comprising a nucleotide sequence encoding porcine circovirus type 2 (PCV-2) open reading frame (ORF) 4, classified in class 424, subclass 204.1;

Group II: Claims 1 (in part) and 2-5, drawn to a composition comprising a nucleotide sequence encoding PCV-2 ORF 4 and ORF 13, classified in class 424, subclass 204.1;

Group III: Claims 6 (in part), 7 and 8, drawn to a composition comprising a nucleotide sequence encoding PCV-2 ORF 4 and an additional pig pathogen, classified in class 424, subclass 199.1;

Group IV: Claims 6 (in part) and 7, drawn to a composition comprising a nucleotide sequence encoding PCV-2 ORF 4 and ORF 13, and an additional pig pathogen, classified in class 424, subclass 199.1;

Group V: Claims 9 (in part), 22 and 23, drawn to a method for reducing PCV-2 viral load in a pig comprising administering a composition comprising a polynucleotide sequence encoding PCV-2 ORF 4, classified in class 435, subclass 5;

Group VI: Claims 9 (in part), 10, 22 and 23, drawn to a method for reducing PCV-2 viral load in a pig comprising administering a composition comprising a polynucleotide sequence encoding PCV-2 ORF 4 and ORF 13, classified in class 435, subclass 5;

Group VII: Claims 11, 13 (in part), 14-19, 20 (in part), 21, 22 and 23, drawn to a method for reducing PCV-2 viral load in a pig comprising administering a composition comprising a nucleotide sequence encoding PCV-2 ORF 4 and an additional pig pathogen, classified in class 435, subclass 5;

Group VIII: Claim 12, drawn to a method for reducing PCV-2 viral load in a pig comprising administering a composition comprising a nucleotide sequence encoding PCV-2 ORF 13, classified in class 435, subclass 5;

Group IX: Claims 13 (in part), 14-19, 20 (in part), 21, 22 and 23, drawn to a method for reducing PCV-2 viral load in a pig comprising administering a composition comprising a polynucleotide sequence encoding PCV-2 ORF 4 and ORF 13, and an additional pig pathogen, classified in class 435, subclass 5;

Group X: Claims 13 (in part), 14-19, 20 (in part), 21, 22 and 23, drawn to a method for reducing PCV-2 viral load in a pig comprising administering a composition comprising a nucleotide sequence encoding PCV-2 ORF 13, and an additional pig pathogen, classified in class 435, subclass 5.

Applicants elect Group VIII, claim 12, with traverse for further prosecution in this application. The Office Action further required restriction to one additional pig pathogen from the group listed in claims 15 and 21; however, claim 12 does not recite an additional pig pathogen. Of course, claim 12 is an open-ended claim, so additional pathogens are not excluded from its scope, as discussed below.

As a traverse, it is initially noted that this carving up of the claims is both inefficient and improper. For starters, the Examiner's attention is directed to MPEP § 803.02, which states:

> If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. (Emphasis added.)

The Examiner's attention is further drawn to MPEP § 803.04, which states:

> Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 *et seq.* Nevertheless, to further aid the biotechnology industry in protecting its

> intellectual property without creating an undue burden on the Office, the Commissioner has decided *sua sponte* to partially waive the requirements of 37 CFR 1.141 *et seq*. and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See *Examination of Patent Applications Containing Nucleotide Sequences*, 1192 O.G. 68 (November 19, 1996).
>
> It has been determined that normally ten sequences constitute a reasonable number for examination purposes.

Claim 9, written independently, recites a Markush group of only two nucleotide sequences, well within the number deemed reasonable by the Commissioner, plus the combination of the two. Therefore, according to the MPEP itself, search and examination of the nucleotide sequences recited in claim 1 does not, as the Examiner asserts in the Office Action, constitute a serious burden. Moreover, the claims of Groups V-X are classified in the same class and subclass, further undermining the Examiner's position that a search of the claims within those groups presents a serious burden.

As further evidence that there is no undue burden in considering PCV-2 ORF4 and ORF13 together, enclosed is a copy of Applicants' U.S. Patent No. 6,943,152 ("the '152 patent"). Claim 1 of the '152 patent is similar to claim 9 of the present application in that it contains a Markush group of two PCV-2 ORFs. Claim 1 of the '152 patent reads, in part: "An immunogenic preparation comprising a complex of: at least one plasmid encoding and expressing *in vivo* in a porcine host an isolated nucleic acid molecule selected from the group consisting of open reading frame (ORF) 1 of porcine circovirus type II (PCV-2) and ORF2 of PCV-2 . . . ." It should be noted that ORF1 and ORF2 of the '152 patent are the SAME as ORF4 and ORF13, respectively, of the present application. If it was not a "serious burden" for the Examiner of the '152 patent to consider the nucleic acid molecules encoding these two ORFs in the same application, Applicants are mystified as to how it has suddenly become so in this application.

According to MPEP § 803:

> [A] serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation of separate classification, or separate status in the art, or a different field of search as defined in MPEP § 808.02. That *prima facie* showing may be rebutted by appropriate showings or evidence by the applicant.

The Examiner has not made a *prima facie* showing of serious burden. As discussed above, Groups V-X do not meet the separate classification standard of MPEP

§ 808.02(A), as they are all classified in class 435, subclass 5. The subjects, particularly the two nucleotides encoding ORF4 and ORF13, have not formed a separate status in the art, and the Examiner has presented no evidence of separate inventive effort by inventors, as is mandated by MPEP § 808.02(B) to show separate status. Clearly there cannot be a separate field of search, since it is not "necessary to search for one of the distinct subjects in places where no pertinent art to the other subject exists," as required by MPEP § 808.02(C). There is simply no possibility that a proper search of a method for reducing viral load of PCV-2 by administering a composition comprising a vector containing and expressing a nucleotide sequence encoding one ORF could be performed in a place "where no pertinent art" to the other ORF would be found. Therefore, the inventions are clearly related, and as such cannot be separated. ("Where . . . the classification is the same and the field of search is the same and there is no clear indication of separate future classification and filed of search, no reasons exist for dividing among related inventions." MPEP § 808.02.

Even if the Examiner argues that a *prima facie* showing has been made, Applicants have provided enough evidence to rebut that showing, as permitted under MPEP § 803. MPEP § 803.02 requires examination of the members of a Markush group sufficiently small in number. MPEP § 803.04 explicitly states that up to ten sequences does not constitute a serious burden except under special circumstances not present in this case. There is simply no basis for the present restriction requirement as drawn.

The present restriction should be redrawn such that Groups V-X, claims 9 and 12-25, already classified in the same class and subclass, are searched and examined together. The reasons for examining claim 9 as it currently reads are enumerated above. At best, the Examiner might require an election of species, in which case Applicants would elect a nucleotide sequence encoding ORF 13. Claims 12, 24 and 25 simply recite subsets of the Markush group of claim 9 and would not require any additional search or examination.

Claims 13-16, 20 and 21 are already included in the scope of claim 9 because the "comprising" language with respect to the composition leaves open the possibility of additional components. Thus, a proper search of claim 9 would include any composition that contains PCV-2 ORF4 and/or ORF13, and would already include the additional limitations recited in claims 13-16, 20 and 21.

Likewise, claims 17-19 further describe the vector of claim 9. A proper search of claim 9 would include all the vectors recited in claim 17. At best, the Examiner might require an election of species, in which case Applicants would elect a DNA plasmid.

Claims 22 and 23 could not possibly require any additional searching, as they would be included in the scope of any claim reciting a method of administering a composition to pigs.

Moreover, there is not a substantial amount of art in this field at all, let alone prior art. Indeed, most of the publications relating to PCV-2 are by the Applicants. Therefore, it is quite unlikely that the Examiner will be overwhelmed with literature or seriously burdened, even performing a thorough search of claim 9.

Finally, enforcing the present restriction requirement would result in inefficiencies and unnecessary expenditures by both the Applicants and the PTO, as well as extreme prejudice to Applicants (particularly in view of GATT, as any divisional applications filed will have a shortened patent term). All of the foregoing arguments justify reconsideration of the restriction requirement or at least rejoinder of Groups V-X. Early action on the merits is solicited.

Respectfully submitted,
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